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(f) There is no right to appear personally before the A.I.D. Administrator.

(g) There is no right to appeal any interlocutory ruling by the ALJ.

(h) In reviewing the initial decision, the A.I.D. Administrator shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the A.I.D. Administrator that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the A.I.D. Administrator shall remand the matter to the ALJ for consideration of such additional evidence.

(j) The A.I.D. Administrator may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment determined by the ALJ in an initial decision.

(k) The A.I.D. Administrator shall promptly serve each party to the appeal with a copy of his/her decision and a statement describing the right of any person determined to be liable for a penalty or assessment to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the A.I.D. Administrator serves the defendant with a copy of his/her decision, a determination that a defendant is liable under § 224.3 is final and is not subject to judicial review.

§ 224.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the A.I.D. Administrator a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the A.I.D. Administrator shall stay the process immediately. The A.I.D. Administrator may order the

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process resumed only upon receipt of the written authorization of the Attorney General.

§ 224.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the A.I.D. Administrator.

(b) No administrative stay is available following a final decision of the A.I.D. Administrator.

§ 224.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the A.I.D. Administrator imposing penalties or assessments under this part and specifies the procedures for such review.

§ 224.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 224.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 224.42 or § 224.43, or any amount agreed upon in a compromise or settlement under § 224.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under the subsection against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 224.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 224.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any

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time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The A.I.D. Administrator has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under § 224.42 or during the pendency of any action to collect penalties and assessments under § 224.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 224.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the A.I.D. Administrator, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the A.I.D. Administrator, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 224.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 224.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 224.10(b) shall be deemed notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

PART 225—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b), unless otherwise noted.

SOURCE: 56 FR 28012, 28020, June 18, 1991, unless otherwise noted.

§ 225.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 225.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 225.102(e) must be reviewed and approved, in compliance with §§ 225.101, 225.102, and §§ 225.107 through 225.117 of this policy,